ASX ANNOUNCEMENT

Actinogen appoints XanaFX Phase 2 trial manager

Sydney, 9 February 2022. Actinogen Medical ASX: ACW ("ACW" or "the Company") is pleased to announce that it has appointed leading clinical research organisation Worldwide Clinical Trials Pty Limited (Australia) ('Worldwide') to manage the recruitment, conduct and general implementation of its XanaFX Phase 2 trial in adolescent boys and young adults with Fragile X Syndrome (FXS).

- **The XanaFX Phase 2 trial:**
  - **Will study cognition, anxiety, sleep and behavioural problems in male adolescents and young adults living with FXS**
  - **Is a randomised, placebo-controlled, double-blind 12-week trial that will enrol 75 patients at up to 26 sites across four countries evaluating two oral dose levels of Actinogen's novel small-molecule drug, Xanamem®[1] using a primary endpoint of the "NIH Toolbox Cognitive Battery for Intellectual Disabilities - Cognition Crystallized Composite Score"**
  - **Results are expected in 2023**
- **Worldwide is a global clinical research organisation specialising in neurological, paediatric, and rare diseases**
- **The Work Order (WO) is a full-service contract that immediately appoints Worldwide to globally manage the XanaFX trial, with oversight from ACW. The WO totals A$13.6 million in addition to the amount of the previous Letter of Intent (LOI) for A$944,724**

The XanaFX trial will study cognition, anxiety, sleep and behavioural problems in male adolescents and young adults possessing the full genetic features associated with FXS. It will be a randomised, placebo-controlled, double-blind, 12-week trial of 5mg and 10mg Xanamem oral doses with 75 patients enrolled in sites in North America, Great Britain, Australia and New Zealand. Results are anticipated in 2023.

Worldwide is a global clinical research organisation specialising in neurological, paediatric, and rare diseases. It commenced operationalising the XanaFX trial and start-up activities after signing a Letter of Intent (LOI) with ACW in November 2021 worth A$944,724 in advance of negotiating and signing a full work order.

The WO contract announced today for an additional A$13.6 million is a full-service contract that appoints Worldwide to globally manage the XanaFX trial, with oversight from ACW.

The WO will remain in force until study completion unless otherwise terminated by ACW or Worldwide with 30 days' notice at cause or 90 days' notice without cause. In the event of termination, Worldwide will be entitled

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[1] The Company announced on 25 November 2021 the expansion of the original XanaFX trial parameters from 50 participants in Australia with a 10mg dose level to 75 enrolments in four countries with an additional 5mg dose level.

to receive payment only for services performed up to the effective date of termination, together with any reasonable fees required in connection with an orderly cessation of all services.

Dr Steven Gourlay, Actinogen CEO and MD, commented:

"We are pleased to finalise a full-service contract with Worldwide Clinical Trials for the management of our Phase 2 Fragile X Syndrome (FXS) trial, the scope of which has recently been expanded to include a larger number of participants and with investigative sites across the USA, UK and NZ in addition to Australia.

"There are currently no treatments approved anywhere in the world for FXS, and the commencement of Actinogen's key XanaFX trial is another important step in our quest to help make a material difference to the quality of life for people and their families living with FXS."

ENDS

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Announcement authorised by the Board of Directors of Actinogen Medical

About Actinogen Medical

Actinogen Medical (ACW) is an ASX-listed, biotechnology company developing a novel therapy for neurological diseases associated with dysregulated brain cortisol. There is a strong association between cortisol and detrimental changes in the brain, affecting cognitive function, harm to brain cells and long-term cognitive health.

Cognitive function means how a person understands, remembers and thinks clearly. Cognitive functions include memory, reasoning, awareness and decision-making, and to a large extent, influence our personality.

We are currently developing our lead compound, Xanamem®, as a promising new therapy for Alzheimer's Disease, Fragile X Syndrome, Depression and other neurological diseases where reducing cortisol inside brain cells could have a positive impact. The cognitive dysfunction, behavioural abnormalities, and neuropsychological burden associated with these conditions is debilitating for patients, and there is a substantial unmet medical need for new and improved treatments.

About Xanamem®

Xanamem's novel mechanism of action works by blocking the production of intracellular cortisol through the inhibition of the 11β-HSD1 enzyme in the brain. Xanamem is designed to get into the brain after it is absorbed in the intestines upon swallowing its capsule.

Chronically elevated cortisol is associated with cognitive decline in Alzheimer's Disease, potentially linked to cognitive impairment and anxiety in Fragile X Syndrome, and cognitive impairment in Depression and other diseases.

The Company has studied 11β-HSD1 inhibition by Xanamem in more than 300 volunteers and patients, so far finding a statistically significant improvement in cognition over placebo in healthy, older volunteers. A series of Phase 2 studies in multiple diseases is being conducted to further confirm and characterise Xanamem's therapeutic potential.

Xanamem is an investigational product and is not approved for use outside of a clinical trial by the FDA or by any global regulatory authority. Xanamem® is a trademark of Actinogen Medical.

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ACTINOGEN MEDICAL ENCOURAGES ALL CURRENT INVESTORS TO GO PAPERLESS BY REGISTERING THEIR DETAILS WITH THE DESIGNATED REGISTRY SERVICE PROVIDER, AUTOMIC GROUP.